



Dental Manufacturing Company
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EC Declaration of Conformity

Manufacturers Name: TOR VM Ltd.

Manufacturers Address: Novatorov str., 7A, bld.2, room 44B, Moscow 119421, Russia
Manufacturing site: Kulibina, 15c, Voronezh, 394029, Russia
Telephone: +7 495 2255417

SRN (Single Registration Number): RU-MF-000016957

Authorized Representative Name (if applicable): Mr. Gregor Kostunov

Authorized Representative Address (if applicable): Untere Seegasse 54, DE-69124, Heidelberg, Germany
Telephone: +49 (17) 626 400 019

SRN (Single Registration Number): DE-AR-000006585

Basic UDI-DI: 463003499POLSTRGT

Name of the Device (s): **Polishing Strips**
(Annex specifying List of Products is an integral part of this Declaration)

Product code: GMDN 35702, Dental Abrasive Strip, Single-Use

Classification: Class I

Notified Body name: for Class I not relevant.

Conformity assessment route: TOR VM uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:
Class I: EC conformity declaration according to Annex IV, Rule 5 and
EN 1041:2008, EN ISO 13485:2016/AC:2018, ISO 14971:2019, EN 1639:2009, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 10993-18:2009, EN 62366-1:2008, BS EN ISO 15223-1:2016

This declaration of conformity is issued under the sole responsibility of TOR VM. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Date of the first CE mark: 10.08.2005

Signature:

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Dr. Oleg Mikhalev
General manager



Place and date (dd.mm.yyyy) of issue:

Moscow, Russia
27.12.2021



List of Products

Catalogue number	Product name
1.050	Strips for Gross Reduction (Coarse)
1.051	Strips for Contouring (Medium)
1.052	Strips for Polishing (Fine)
1.053	Strips. Universal Kit for Contouring
1.054	Strips. Universal Kit for Finishing
1.055	Polishing Strips. Universal Kit
1.384(1)	Proxicut Saw Blades
1.384(2)	Proxicut Saw Blades
1.385C(1)	Proxicut Diamond Strips, Coarse
1.385C(2)	Proxicut Diamond Strips, Coarse
1.385M(1)	Proxicut Diamond Strips, Medium
1.385M(2)	Proxicut Diamond Strips, Medium
1.385F(1)	Proxicut Diamond Strips, Fine
1.385F(2)	Proxicut Diamond Strips, Fine
1.370	Do-All Proxicut System
1.386	Metal Strips for Tartar Removal
1.150	Metal Diamond Strips (Coarse)
1.151	Metal Diamond Strips (Medium)
1.152	Metal Diamond Strips (Fine)
2.150	Metal Diamond Perforated Strips (Coarse)
2.151	Metal Diamond Perforated Strips (Medium)
2.152	Metal Diamond Perforated Strips (Fine)

Dr. Oleg Mikhalev,
General manager
December 27, 2021

